

Re: Libby RfC - SAB request Fw: Request For Additional Information [my interpretation of what is being requested]

Thomas Bateson to: Danielle DeVoney

01/24/2012 10:47 AM

From: Thomas Bateson/DC/USEPA/US

To:

Cc: Leonid Kopylev/DC/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Krista Christensen/DC/USEPA/US@EPA, Bob Benson/R8/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA

Regarding the last paragraph, my interpretation is that the request is for the final analytic files that the regression analyses were run on. Not the raw source files used to construct the final analytic files.

We have these in hand and could transmit if we get permission from Region 8 and UC. As for de-identification, I spoke with Krista and there are two data elements that might be construed as identifying: date of hire and date of termination. For each date, we could truncate to just the year of hire and year of termination.

It seems like we could produce these files now, circulate within NCEA and R8 for quick QA/QC, and ask R8 to get approval from UC.

At the same time, we should be asking if R8 and UC are willing to share the raw source files should those be specifically requested.

Tom

Danielle DeVoney---01/24/2012 10:36:05 AM---Hi - Yes, they did request the full data set (see #5 in the first e-mail in this exchange). This i

From: Danielle DeVoney/DC/USEPA/US
To: Leonid Kopylev/DC/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Krista Christensen/DC/USEPA/US@EPA, Bob Benson/R8/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA
Date: 01/24/2012 10:36 AM
Subject: Re: Libby RfC - SAB request Fw: Request For Additional Information

Hi -

Yes, they did request the full data set (see #5 in the first e-mail in this exchange). This is the written request from the SAB. So regardless of how we interpret #1, they are definitely asking for the raw data (#5). I specifically asked Diana to put her verbal request in writing , so that we were not wasting effort. Although it is true that when she and I spoke I understood her request for the full data set (#5) and her discussion of better information on the sub vs full data sets as related [Which likely influenced how I interpreted the written request.]

On reading Glinda's e-mail - I believe her comments are a better interpretation of the wording from the SAB panel member (likely an Epi person) so I forwarded that to Diana for clarification from the SAB panel

member. If indeed what the requester wants is summary statistics as described by Glinda - then we will need to send these. Since neither our full or subcohort analyses follow the data as presented in either publication, the summary statistics will be different than either publication (Rohs et al 2007 or Lockey et al., 1984).

Once we put together summary statistics, and get a clean copy of the full data we can forward to the SAB. If it is a nominal LOE to include a spreadsheet for each of the two modeling efforts, it would likely be helpful. When reviewers ask for raw data - it seems like they are likely to try and reproduce the modeling. I believe they would have a hard time reproducing our two populations as modeled based on our description.

Danielle

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Leonid Kopylev---01/23/2012 07:55:45 PM---This also struck me as quite an inconsistency. It is as someone does not really expects the raw data

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To: Glinda Cooper/DC/USEPA/US@EPA
Cc: Bob Benson/R8/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, Danielle
DeVoney/DC/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Deborah
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Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA
Date: 01/23/2012 07:55 PM
Subject: Re: Libby RfC - SAB request Fw: Request For Additional Information

This also struck me as quite an inconsistency. It is as someone does not really expects the raw data....

Glinda Cooper---01/23/2012 07:43:21 PM---To me, #1 below is ambiguous, and would warrant clarification about what the reviewer actually wants

From: Glinda Cooper/DC/USEPA/US
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Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA
Date: 01/23/2012 07:43 PM
Subject: Re: Libby RfC - SAB request Fw: Request For Additional Information

To me, #1 below is ambiguous, and would warrant clarification about what the reviewer actually wants. If I asked someone to provide me "more basic data description for the primary subset and full cohort..." I would **NOT** want to be given a dataset. What I would like to see is descriptive statistics (i.e., summary statistics - mean, median, interquartile range, 95th percentile etc. - describing the distribution of key variables such as age first exposure, length of follow-up, exposure measures, etc. I would also want to see the amount of

missing data for key variables. So, before you go to the trouble of creating datasets, I think it's worth looking at what is actually in the document (from a descriptive statistics point of view), and what can easily be generated to fill in the gaps, and then asking if this is sufficient.
Glinda

-----Danielle DeVoney/DC/USEPA/US wrote: -----

To: Leonid Kopylev/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Krista Christensen/DC/USEPA/US@EPA, Bob Benson/R8/USEPA/US@EPA
From: Danielle DeVoney/DC/USEPA/US
Date: 01/23/2012 06:33PM
Cc: Deborah McKean/R8/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA
Subject: Libby RfC - SAB request Fw: Request For Additional Information

Hi all,

Please see the request by SAB below for both raw data and modeling results to support the RfC. It seems like we could fulfill the request for our modeling results directly, but may need to coordinate with Dr. Lockey for the data requests.

A) I believe NCEA would be the lead for items 2,3 an 4 below corresponding to more information on the model results provided in tables E-1, E-2, E-3 E-4 and E-5. Can we provide this information as requested? How long will it take to prepare for transmittal to the SAB? (Remembering what we provide will be available to the public - so we need to format it for clarity.)

Krista - can you be the lead on this?

B) For Item 1 below "More basic data description for the primary subset and full cohort used for analysis": I interpret this as more than a verbal description - and it might be useful to provide the actual data input file to the model in addition to a brief description (taken from the text?). If we do this, we need to check with Univ. of Cincinnati regarding sharing these data.

For each analysis (full and subcohort) can we provide a spreadsheet of the relevant data input to our modeling? (removing personal identifiers)

If we need clearance form Univ of Cincinnati to provide these to the SAB - should we send them the files for review prior to sending to the SAB?

C) On the final item - it would seem we need to contact Univ. of Cincinnati for permission to forward the complete data file (minus identifiers.)

Bob - can you take the lead on this? Should we ask Dr. Lockey if they would like to provide the clean file so they have direct control over what is released?

Bob - Do you know what our contract with Univ. of Cincinnati say with respect to our ability to share the raw data they provided?

It is possible we could receive similar requests for additional information on the cancer models.

Danielle

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----- Forwarded by Danielle DeVoney/DC/USEPA/US on 01/23/2012 06:02 PM -----

From: Diana-M Wong/DC/USEPA/US
To: Danielle DeVoney/DC/USEPA/US@EPA, Bob Benson/R8/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA
Date: 01/23/2012 05:35 PM
Subject: Request For Additional Information

Dear All,

A SAB Panel member is requesting for more information on the following for evaluation of EPA's analysis on estimating the RfC:

- 1) *More basic data description for the primary subset and full cohort used for analysis.
- 2) *Estimates of the regression coefficient and its SE for exposure
in all models (refer to Table E-1).
- 3) *All parameter estimates in the models in Table E-2.
(Specifically, all models with ln(CHEEC) as exposure at a 10 year lag. That would be the logistic, probit, 3-parameter logistic, Dichotomous Hill, and Michaelis-Menten).
- 4) *All coefficient estimates for the model assessing smoking
(refer to Table E-4, also E-5)
- 5) *Raw data file used in the analysis

Please make this information as soon as you can. Thanks.

Diana

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